

Applicants: Janaswamy Madhusudana Rao et al.
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REMARKS

Claims 1-7 and 9-12 were pending and under examination. By this Amendment, applicants have amended claims 1-7. Support for amended claim 1 may be found in the specification *inter alia* on page 4, lines 18-22, on page 5, lines 1-10 and on page 5, lines 31-33. Claims 2-7 have been amended to correct certain misspellings. Applicants maintain that no issue of new matter is raised by these amendments. Accordingly, claims 1-7 and 9-12 as amended will be pending in the subject application upon entry of this Amendment.

Objection To The Abstract

The Examiner objected to the phrase "The present invention" in the Abstract. In response, applicants have herein replaced the Abstract with a new Abstract which recites "Provided herein" rather than "The present invention", thereby rendering moot the Examiner's ground of objection. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this ground of objection.

Rejections Under 35 U.S.C. § 112, First Paragraph

The Examiner rejected claims 1-4, 6, 7, and 9-12 under 35 U.S.C. § 112 as allegedly failing to provide prior support or antecedent basis for the language in Claim 1. Specifically, the Examiner alleged that the original concept of the invention has been broadened to encompass compositions comprising a single powdered plant of the botanical constituents recited in the Markush group of Claim 1. The Examiner alleged that it is clear from the specification that the Applicant intended to include and not exclude compositions comprising each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions, wherein the equal proportions of the botanicals comprising the composition has a value that is greater than zero. The Examiner stated that the recitation of the claim limitations is deemed new matter.

In response, but without conceding the correctness of the Examiner's ground of rejection, applicants have amended claim 1 to recite a herbal composition for the treatment of gastric ulcer, said composition comprising powdered plant parts selected from the group consisting of

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Asparagus racemosus, Glycyrrhiza glabra, Sesamum indicum, Musa sapientum, Trachyspermum roxburghianum, Cyclea peltata, Embelia ribes, Coriandrum sativum, Ferula asafetida, Aloe barbadensis and Evolvulus alsinoides and one or more pharmaceutically acceptable additives or carriers, wherein said composition comprises each of *Asparagus racemosus, Glycyrrhiza glabra, Sesamum indicum, Musa sapientum and Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero. Accordingly, applicants maintain that the Examiner's ground of objection has been obviated and respectfully request that this ground of rejection be reconsidered and withdrawn.

Rejections Under 35 U.S.C. § 112, Second Paragraph

The Examiner stated that claims 1-7 and 9-12 remain rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner alleged that it is unclear how the instantly claimed composition can "essentially comprise *Asparagus racemosus, Glycyrrhiza glabra, Sesamum indicum, Musa sapientum and Trachyspermum roxburghianum* in about equal proportions", when the scope of the preamble encompasses subject matter to compositions that can comprise powdered plants of a single botanical selected from a Markush group consisting of eleven claim-designated members, which recites powdered plants of botanicals other than the five recited in the aforementioned phrase. In addition, the Examiner stated that claims 1-7 recite the terms: "*Evolvulus aidinodes*", "*Trachaparmum roxburghicinum*" and "*Cyclea peleta*" which appear to be misspelled and thus unclear.

In response, but without conceding the correctness of the Examiner's ground of rejection, applicants have amended claim 1 to recite that the composition comprises each of *Asparagus racemosus, Glycyrrhiza glabra, Sesamum indicum, Musa sapientum and Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero. In addition, applicants have amended the claims 1-7 to correct all misspellings of botanical names. Accordingly, applicants maintain that the Examiner's grounds of rejection have been obviated.

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In view of these remarks, applicants maintain that claims 1-7 and 9-12, as amended, satisfy the requirements of 35 U.S.C. § 112, second paragraph.

Substitute Specification

On page 9 of the February 9, 2007 Final Office Action, the Examiner indicated that there appear to be misspellings of botanicals not only in the claims but throughout the specification as well. The Examiner stated that correction of these misspellings is required.

In response, applicants submit a clean version of a substitute specification attached hereto as **Exhibit A** and a version of the substitute specification marked to show the changes relative to the previous version thereof attached hereto as **Exhibit B** in accordance with 37 C.F.R. §1.125(c). In accordance with 37 C.F.R. §1.125(b), applicants maintain that the substitute specification contains no new matter. Applicants respectfully request that the Examiner enter the attached substitute specification and withdraw this ground of objection.

Rejections Under 35 U.S.C. §102

Hong-Yue, Dehpour et al. Or Christina et al.

The Examiner rejected claims 1 and 7 under 35 U.S.C. § 102(b) as allegedly anticipated by Hong-Yue, Dehpour et al., or Christina et al. Hong-Yue teaches an antipeptic ulcer comprising powdered licorice and clove, Dehpour teaches a composition comprising powdered root of *Glycyrrhiza glabra* that is used to coat ibuprofen to treat gastric lesions and Christina teaches a composition comprising root powder of *Cyclea peltata* and milk.

In response, applicants maintain that Hong-Yue discloses a composition comprising comprising powdered licorice and clove. Dehpour et al. disclose a composition comprising *Glycyrrhiza glabra*. Christina et al. disclose a composition comprising *Cyclea peltata* and milk. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Accordingly, applicants maintain that none of these cited references anticipate claim 1 as now amended.

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Yoshida

The Examiner rejected claims 1 and 10 under 35 U.S.C. §102(b) as allegedly anticipated by Yoshida. Yoshida teaches a composition comprising a powdered seed oil extract of *Sesamum indicum* that is beneficial for peptid ulcers.

In response, applicants maintain that Yoshida discloses a composition comprising a powdered seed oil extract of *Sesamum indicum* that is beneficial for the treatment of ulcers. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Yoshida only discloses the use of *Sesamum indicum* alone and therefore does not anticipate amended claim 1.

Lewis et al.

The Examiner rejected claims 1 and 11 under 35 U.S.C. §102(b) as allegedly anticipated by Lewis et al. Lewis teaches a composition comprising unripe fruit powder of *Musa sapientum* and food having antiulcerogenic properties.

In response, applicants maintain that Lewis et al. disclose a composition comprising unripe fruit powder of *Musa sapientum* and food having anti-ulcerogenic properties. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Lewis et al. only disclose the use of *Musa sapientum* without the use of the other ingredients and therefore does not anticipate amended claim 1 or claim 11 dependent therefrom.

Goel et al., Sakakibara et al., McAnalley, or Purohit et al.

The Examiner rejected claim 1 under 35 U.S.C. § 102(b) as allegedly anticipated by Goel et al., Sakakibara et al., McAnalley, or Purohit et al. Goel teaches a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Musa sapientum* and water. Sakakibara teaches a composition comprising powdered plant parts of *Coriandrum sativum* and a food product. McAnalley teaches a composition for the treatment of gastric ulcer comprising powdered *Aloe vera* and also teaches a powdered *Aloe Vera* in a phosphate buffer. Purohit et al.

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teach a herbal composition for the treatment of gastric ulcer comprising fruit powder of *Evolvulus alsinoides* in an alcohol solvent buffer.

In response, applicants maintain that Goel et al. disclose a composition comprising fruit powder of *Musa sapientum* and water for the treatment of gastric ulcers. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Goel et al. only discloses the use of *Musa sapientum* without the use of the other ingredients and therefore does not anticipate amended claim 1.

Sakakibara discloses a composition comprising powdered plant parts of *Coriandrum sativum* and a food product. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Sakakibara does not anticipate the subject matter of the application as it also fails to teach the required use of the five above ingredients.

McAnalley discloses a composition for the treatment of a gastric ulcer comprising powdered *Aloe vera*. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Accordingly, applicants maintain that McAnalley does not anticipate a composition which requires the use of *Aloe barbadensis* in conjunction with five other ingredients as required in amended claim 1.

Purohit et al. disclose a composition for the treatment of a gastric ulcer comprising fruit powder of *Evolvulus alsinoides* in an alcohol solvent buffer. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Accordingly, Purohit et al. do not anticipate a composition which requires the use of *Evolvulus alsinoides* in conjunction with five other ingredients as recited in amended claim 1.

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Rao et al. or Singh et al.

The Examiner rejected claims 1 and 6 under 35 U.S.C. § 102(b) as allegedly anticipated by Rao et al. or Singh et al. Rao teaches a composition comprising a fruit powder of *Embelia ribes* and a plant oil and Singh teaches a fruit powder of *Embelia ribes* and other plant extracts.

In response, applicants maintain that Rao et al. discloses a composition comprising a fruit powder of *Embelia Ribes* and plant oil and Singh et al. disclose a fruit powder of *Embelia Ribes* and other plant extracts. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Rao et al. and Singh et al. only disclose the use of *Embelia Ribes* alone and therefore does not anticipate amended claim 1 or claim 6 dependent therefrom.

Haney or Hankey as evidenced by Johnson et al.

The Examiner rejected claims 1 and 12 under 35 U.S.C. §102(b) as allegedly anticipated by Haney or Hankey as evidenced by the teachings of Johnson et al. Haney teaches a composition comprising powdered *Ferula asafetida* in combination with a mixture comprising salt, a mixture of powdered mustards, sugar, powdered turmeric, powdered milk and powdered dextrin and Hankey teaches a composition comprising powdered *Ferula asafetida* in alcohol.

In response, applicants maintain that Haney discloses a composition comprising powdered *Ferula asafetida* in combination with a mixture comprising salt, a mixture of powdered mustards, sugar, powdered turmeric and powdered dextrin. Hankey discloses a composition comprising *Ferula asafetida* in alcohol. Johnson et al. disclose that powder asafetida is prepared from resin obtained from the roots and rhizomes of the plant. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Accordingly, applicants maintain that the above cited references do not anticipate a composition with *Ferula asafetida* in conjunction with at least five other ingredients.

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Palpu et al.

The Examiner rejected claims 1 and 9 under 35 U.S.C. § 102(e) as allegedly anticipated by Palpu et al. Palpu teaches a herbal composition for the treatment of gastric ulcer comprising powdered tuber of *Asparagus racemosus* and other plant parts of other plants.

In response, applicants maintain that Palpu et al. disclose an herbal composition for the treatment of gastric ulcer comprising powdered tuber of *Asparagus racemosus* and other powdered plant parts of other plants. Claim 1, as amended requires the composition to be comprised of at least five ingredients including *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum*. Accordingly, applicants maintain that Palpu et al. do not anticipate a composition wherein *Asparagus racemosus* is one of five required ingredients as recited in amended claim 1.

Applicants maintain that none of the above cited references recite each and every element recited in amended claim 1 and therefore do not anticipate claim 1 as amended or any claims dependent therefrom. Applicants respectfully request that the Examiner reconsider and withdraw the grounds of rejection under 35 U.S.C. §102.

Rejections Under 35 U.S.C. §103

On page 17 of the February 9, 2007 Final Office Action, the Examiner rejected claims 1, 2 and 6-10 under 35 U.S.C. §103(a) as allegedly unpatentable over Palpu (D*), Hong Yue (A*), Dehpour (V), Yoshida et al. (N), Lewis et al. (W1) and Johnson (W). Specifically, the Examiner alleged that each of the cited prior art teaches a composition for the treatment of ulcers comprising an ingredient recited in claim 1. The Examiner conceded that the prior art does not teach a composition comprising each of the instantly claimed ingredients as listed in claim 1, but alleged that one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claim-designated ingredients in the making of the instantly claimed composition because at the time the invention was made, each of the powdered plant parts of *Asparagus racemosus* tuber, *Glycyrrhiza glabra* root, *Sesamum indicum* seed, unripe fruit of *Musa sapientum* and *Trachyspermum roxburghianum* were known in the art of herbal medicine to be useful for the treatment of treating gastrict ulcer.

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The Examiner further alleged that it would have been obvious to one of ordinary skill in the art to add any of the claimed ingredients in the making of the claimed composition because it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The Examiner further alleged that each of the references indicate various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations, as well as the experimental parameters for manufacturing thereof, are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

In response, applicants respectfully traverse the Examiner's rejection.

Claim 1 as now amended provides a herbal composition for the treatment of gastric ulcer, said composition comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsinoides* and one or more pharmaceutically acceptable additives or carriers, wherein said composition comprises each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero.

Applicants first note that none of the prior art references teach the use of such ingredients together. Applicants further note that the combination of the ingredients in applicants' composition provides unexpected results. Applicants maintain that the composition as now recited in claim 1 exhibits a higher potency for treating gastric ulcers which is an unexpected result of combining the above-listed powdered plant ingredients. Applicants maintain that the composition of claim 1 exhibits synergistic properties as shown in Table 8, on page 18 of the application as filed. Applicants also direct the Examiner's attention to the Table on page 12 which shows the increased protection of the composition of the invention over Omeprazole; on page 14 at Table 3 and lines 14-16 which shows the composition has superior

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results to a combination of Omperazole and ethanol. Applicants further direct the Examiner's attention to page 16, Table 5, which demonstrates the superior protection afforded by the present composition. Accordingly, applicants maintain that the claimed composition produces an unexpected result and is therefore unobvious over the above cited references in combination.

On page 20 of the February 9, 2007 Final Office Action, the Examiner rejected claims 1, 2 and 6-10 under 35 U.S.C. §103(a) as being unpatentable over Palpu (D*), Hong Yue (A*), Dehpour (V), Yoshida et al. (N), Lewis et al. (W1) and Johnson (W) in view of Khrenova et al. (U1), McAnalley (E*), Yang (O) and Purohit et al. (X2). The Examiner alleged that the combined teachings of the Palpu (D*), Hong Yue (A*), Dehpour (V), Yoshida et al. (N), Lewis et al. (W1) and Johnson (W) teach a composition for the treatment of gastric acid essentially comprising the ingredients listed in claim 1 in about equal proportions and one or more pharmaceutically acceptable additives or carriers. The Examiner conceded that the Palpu, Hong Yue, Dehpour, Yoshida et al., Lewis et al. and Johnson do not teach the composition wherein the powdered plant parts are *Coriandrum sativum*, *Aloe barbadensis*, *Ferula asafetida* and *Evolvulus alsinoides*, but the Examiner alleged that it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredients to the composition taught by the combined teachings of Palpu, Hong Yue, Dehpour, Yoshida et al., Lewis et al. and Johnson because Khrenova et al., McAnalley, Yang and Purohit et al. taught that beneficial functional effect of each of the claim-designated ingredients. The Examiner alleged that one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation to add any of the claim-designated ingredients of powdered plant parts of *Coriandrum sativum*, *Aloe barbadensis*, *Ferula asafetida* and *Evolvulus alsinoides* to the composition taught by the combined teachings of Palpu, Hong Yue, Dehpour, Yoshida et al., Lewis et al. and Johnson to provide the instantly claimed invention because each claim designated ingredients were in the art of herbal medicine as being useful in the treatment of gastric ulcer, as by the prior art teachings.

In response, applicants respectfully traverse the Examiner's rejection.

Claim 1 as now amended provides a herbal composition for the treatment

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of gastric ulcer, said composition comprising powdered plant parts selected from the group consisting of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum*, *Trachyspermum roxburghianum*, *Cyclea peltata*, *Embelia ribes*, *Coriandrum sativum*, *Ferula asafetida*, *Aloe barbadensis* and *Evolvulus alsinoides* and one or more pharmaceutically acceptable additives or carriers, wherein said composition comprises each of *Asparagus racemosus*, *Glycyrrhiza glabra*, *Sesamum indicum*, *Musa sapientum* and *Trachyspermum roxburghianum* in about equal proportions by weight and such about equal proportion has a value greater than zero.

Applicants again note that none of the prior art references teach the use of such ingredients together. Applicants further note that the combination of the ingredients in applicants' composition provides unexpected results. Applicants maintain that the composition as now recited in claim 1 exhibits a higher potency for treating gastric ulcers which is an unexpected result of combining the above-listed powdered plant ingredients. Applicants maintain that the composition of claim 1 exhibits synergistic properties as shown in Table 8, on page 18 of the application as filed. Applicants also direct the Examiner's attention to the Table on page 12 which shows the increased protection of the composition of the invention over Omeprazole; on page 14 at Table 3 and lines 14-16 which shows the composition has superior results to a combination of Omperazole and ethanol. Applicants further direct the Examiner's attention to page 16, Table 5, which demonstrates the superior protection afforded by the present composition. Accordingly, applicants maintain that the claimed composition produces an unexpected result and is therefore unobvious over the above cited references in combination.

In view of the remarks above, applicants maintain that claim 1 as amended and claims dependent therefrom are not obvious over the cited prior art references and respectfully request that the Examiner reconsider and withdraw the grounds of rejection under 35 U.S.C. §103.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee, other than \$2,450 for a four-month extension of time and Request for Continued Examination, is deemed necessary in connection with the filing of this Amendment. However, if any other fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

 116/08

John P. White	Date
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